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Treatment outcomes of patients on antiretrovirals after six months of treatment, Khami Clinic, Bulawayo, Zimbabwe

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Abstract

Objective: To describe treatment outcomes of patients on anti-retrovirals at six months of treatment.

Study Design: We conducted pre-intervention post intervention surveys using a pretest-post test design.

Setting: Khami Municipal Clinic, Bulawayo.

Subjects: We interviewed consecutive patients eligible to receive antiretroviral drugs (ARVs). All patients had a history of TB treatment and a CD4 count less than 200 cells/mm.³

Main Outcome Measures: Mean change in CD4 count, weight, body mass index, and Karnofsky performance measured before and at six months of antiretroviral treatment.

Results: 72 subjects were interviewed at baseline, their median age was 38 years (Q₁ 32 years, Q₃ 43 years). Of these, 17 (24%) died before six months of treatment. Three (4%) defaulted treatment follow up. A total of 52 respondents were alive and interviewed at six months though only 50, had repeat CD4 counts at six months. Among the 50 survivors, the mean CD4 count at six months was significantly higher than at baseline ($p=0.0003$). There was a 4.2 point statistical significant increase in the mean weight from baseline ($p=0.0005$). Similarly, the mean Body Mass Index (BMI) significantly increased by 1.5 kg/m² from baseline, ($p=0.001$). The mean Karnofsky performance increased from 89% at baseline to 95% at six months ($p=0.0004$). The researchers noted that patients on TB treatment were being deferred antiretroviral therapy until they completed TB treatment.

Conclusion: The Khami project bears testimony that even in a resource poor setting; treatment of HIV/AIDS with antiretroviral drugs is feasible. We recommend early treatment initiation for those on TB treatment in line with national guidelines.

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Introduction

It was in 1985 that the first case of HIV tested positive in Zimbabwe. The AIDS epidemic has grown since then to become one of the most serious public health challenges to ever face the nation.¹ According to the 2003 HIV estimates, 24,6% of adults aged 15 to 49 years were infected.² Whilst they cannot cure

HIV/AIDS, treatment of HIV with Highly Active Antiretroviral Therapy (HAART) can transform the natural course of HIV infection by reducing morbidity and mortality as has been observed in many industrialized countries.³ It is recommended for patients with symptomatic AIDS, WHO Adult Stage IV and advanced Stage III irrespective of the CD4 cell count or total lymphocyte count. If CD4 cell count

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monitoring is unavailable, treatment is recommended for symptomatic patients with total lymphocyte counts below 1200/mm.⁴

In Zimbabwe, lack of access to antiretroviral therapy (ART) was declared an emergency in May 2003, paving a way to improve care of People Living with HIV and AIDS (PLWA), better access to ARVs and authorization to import generics.⁵ The ART programme was implemented in public health institutions using the phased out approach from five learning sites, namely Harare and Mpilo (referral Central Hospitals), Howard hospital (rural mission), Bulawayo City (local authority) and Triangle Hospital (private/public).⁶ In 2003, it was estimated that 273 000 had advanced AIDS and needed antiretroviral therapy. As of 2004 however, only 8 500 (4.5%) were on ARVs countrywide.⁶

Bulawayo city is the second largest city in Zimbabwe with a total population of 691 728 and a growth rate of 1.1%.⁷ Trends in annual death rates have more than doubled since the late 1980s and this has been attributed to the HIV pandemic.⁸ Death rates among the economically productive 25 to 44 year age group have increased seven to eight fold since 1990. Most deaths in this age group were from AIDS and its complications.⁹ In 2002 the death rate in this age group was as high as 23 per 1000 population. These high death rates are bound to have profound adverse effects in the socio-economic development of communities.⁹

Bulawayo city introduced antiretroviral (ARV) drugs at Khami Clinic in September 2004. The first group of patients was put on ARVs on the 9th September 2004. This project is also being used as one of the five learning sites for the national ARV roll out programme. The City Health Department provides staff, a team of one medical officer, two nurses supervised by a Sister-in-Charge of the clinic and a data entry clerk to run the project. Initiation of the project was made possible through financial and technical support from John Snow Incorporation (JSI). They made a commitment to provide all ARV drug requirements for at least 200 patients. The funding also covers the costs of running any laboratory samples, which are all done, at Mpilo Central Hospital.

Potential beneficiaries are patients with a history of TB treatment and a CD4 count less than 200 cells/mm³. Community nurses at local clinics identify potential beneficiaries through TB registers and sensitize them. They are also encouraged to bring along their wives and children for assessment and possible treatment if they also have a CD4 count less than 200 cells/mm³. Treatment for those with active TB is deferred until completion of TB treatment. Initial pre-test and post test counseling for HIV is done at the local clinic before referral to Khami Clinic. When received at Khami Clinic, the patients go through counseling sessions by the nurses. These sessions cover among other things, issues of status disclosure; treatment adherence; safer sex and risky behavior reduction. Only those willing to disclose their status to someone trusted, who in turn

becomes a treatment partner to monitor adherence are eligible to receive treatment. Initiation of treatment is by the medical officer manning the clinic. The patients are put on a cocktail of Stavudine, Lamivudine and Niverapine. Those who develop severe skin reactions to Niverapine are switched on to Efavirenz and those who develop severe peripheral neuropathy to Stavudine are switched on to Zidovudine.

Follow up review of these patients is scheduled at 2 weeks of treatment, then monthly thereafter. The treatment partner is expected to supervise treatment and sign on a 'Daily Observed Treatment Card' after each dose is taken.

When the first patient was put on ARVs on the 9th of September 2004, the local authorities were keen on knowing whether these drugs would yield any benefit among the intended beneficiaries in the Khami Clinic setting. This study offered an opportunity to describe treatment outcomes in the first 6 months of treatment.

Materials and Methods

We conducted a pre-intervention post-intervention survey using pretest-pos test design. An interview was done at enrollment to obtain baseline data on CD4 count, body weight, body mass index, Karnofsky performance and other variables of interest. This was followed by a post-intervention survey to obtain data on certain variables and evaluate the effectiveness of the intervention at six months after ARVs initiation.

We conveniently sampled consecutive patients who were being recruited to receive ARVs between the 9th September 2004 and 28th January 2005. We included all participants enrolled during the limited time available to complete fieldwork. Time line projections for the project had envisaged that by the end of January 2005, at least 100 patients would have been on ARVs. To be enrolled into the study one had to be a resident of Bulawayo who had never been on ARV treatment, with a documented history of TB treatment in the past 10 years and a CD4 count less than 200 cells/mm³ at baseline.

We used an interviewer-administered questionnaire to collect socio-demographic data, casual sex partnering and condom use at baseline. An exit interview at six months was also done to describe household food security during the six months of treatment, any changes in casual sex partnering, condom use and drug side effects experienced during the 6 months treatment. The patients' files were also checked at six months for any documented side effects.

The Khami project has an inherent mechanism to monitor treatment adherence, which was made use of in this study. At each visit, patients are given more medication than required and instructed to return all medication bottles and unused pills at their next visit. The returned pills are counted and compared to what was given. This is used to compute a percentage rating of treatment adherence, as the proportion of tablets swallowed without vomiting of the expected in a given

month. This rating is documented in the patient's file at each review. For our study, we computed the mean adherence rating for each patient over the study period. A daily treatment card signed by a treatment partner at home after each dose was taken was also checked at six months.

Laboratory reports of CD4 counts done before treatment were used to compute the mean CD4 count at baseline, which was compared to the mean count at six months of treatment. This was used to objectively assess the immunological response to treatment.

Clinical response to treatment was assessed by comparing the mean Karnofsky performance at baseline, to that at six months of treatment as well as the mean weight of the study subjects at baseline compared to that at six months. The weight and height at baseline was used to compute the Body Mass Index (BMI), which was also compared to computations for measurements at six months of treatment. This variable was used as a proxy of changes in nutritional status.

We captured and analyzed data using Epi-info 2002 statistical package to generate frequencies and tables. The paired t-test and Chi-square statistics were used to test for statistical significance at 95% confidence level. Permission to do the study was obtained from the Director, Bulawayo Health Services and the Department of community medicine, University of Zimbabwe. Verbal consent was obtained from study participants.

Study Limitations.

There was potential for recall bias on events that had occurred over the six month period. The researchers tried to minimize the effects by checking information given during interviews against recorded information in patients' files and out patients' cards. Only patients who had a history of TB treatment were enrolled into the study. This presents a special group who have had an experience of taking TB drugs for at least six months, and may be better motivated and more likely to comply to taking ARV medication than the general populace.

Study participants were only assessed on recruitment when baseline data was collected, and at six months following initiation of ARVs. This meant that any changes in baseline indicators (CD4 Count; patient weight; Karnofsky performance; BMI) during the interval between time of subject enrolment and six months after treatment could not be determined. Time line changes could not be tracked because patients were not interviewed between recruitment and at six months.

Certain information like that of side effects for all patients recruited relied on accurate and complete documentation by the attending medical officer. This could have been a source of information bias.

Results

Demographic data.

There were 72 respondents interviewed at baseline.

Their median age was 38 years Q_1 32 years, Q_3 43 years. Table 1 shows demographic characteristics of the study population at baseline. Of the 72 respondents enrolled at baseline, 17 (24%) died before completing six months of treatment and three (4%) defaulted treatment follow up. A total of 52 respondents were alive and on treatment at six months. These were interviewed at six months though only 50 had repeat CD4 counts done at six months and only these 50 were used in the treatment outcome analysis.

Table 1: Frequency distribution of demographic variables of respondents at baseline, Khami Clinic, September 2004 to July 2005.

Variable		Frequency (n=72)
Age (yrs)	Median (Q_1 ; Q_3)	38 (32;43)
Gender	Female*(%)	39 (54)
	Male (%)	33 (46)
Marital Status	Married (%)	24 (33)
	Widowed (%)	21 (29)
	Single (%)	15 (21)
	Divorced/Separated (%)	11 (15)
	Cohabiting (%)	1 (1)
Religion	Nil (%)	25 (35)
	Protestant (%)	18 (25)
	**African Apostolic (%)	13 (18)
	Pentecostal (%)	11 (15)
	Catholic (%)	5 (7)
Education	Nil (%)	1 (1)
	Primary* (%)	17 (24)
	Secondary (%)	50 (69)
	Tertiary (%)	4 (6)

(%) Rounded off to the nearest whole number

** White garmented religious sect

Among those who died, the median duration on treatment before dying was observed to be 63 days, Q_1 =32 days; Q_3 =72 days, implying that a quarter died in the first month or (32 days) of treatment and half in the first two months or (63 days) of treatment. A comparison of baseline variables of survivors and those who died is shown in Table II. It was observed that those who died were more likely to score lower on the Karnofsky scale than those who survived, at baseline, p value: 0.02.

Table II: Comparative distribution of baseline variables between respondents who survived and those who died, Khami Clinic, September 2004 to July 2005.

Variable	Survivors (N ₁ :52)	Died (N ₂ :17)	*t-statistic	**p value
Median age (Q_1 ; Q_3)	38 (32;43)	37 (33;45)	-	-
Female gender (%)	39 (54)	11 (55)	-	-
Baseline mean CD4 Count (cells/mm ³)	79.8	66.1	0.86	0.12
Baseline mean weight (kg)	54.5	50.8	1.14	0.09
Karnofsky performance (%)	88.6	75.9	6.08	0.02

*Independent t-test used

**95% level of significance used

Treatment Outcomes.

(I) Immunological response.

Among survivors, the mean CD4 count was 80 cells/mm³ at baseline, compared to 200 cells/mm³ at six months. The increase from baseline was found to be statistically significant, p value: 0.0003. The median increase in CD4 count from baseline was 110 cells/mm³, Q₁=68; Q₃=170. The majority, 15 (30%), had an increase in CD4 count from baseline in the range, 101 to 150 cells/mm³. Only three (6%) had CD4 counts decreasing from baseline. As the magnitude of increase in CD4 count from baseline got larger, so did the increase in mean weight from baseline. There was an inverse relation observed in the magnitude of increase in CD4 count and the CD4 count at baseline, implying that those who had very large increases in CD4 count were likely to have had very low CD4 counts at baseline. Table III shows magnitude of changes in CD4 count from baseline among survivors.

Table III: Changes in CD4 count from baseline to six months after ARV initiation in relation to other variables among survivors on ARVs at Khami Clinic.

Magnitude of increase CD4 count: cells/mm ³	Freq. (%) n:50	Mean weight increase (kg)	Mean CD4 (baseline)	Mean Karnofsky (baseline)
* < 0	3 (6)	1.7	153.3	86.7
0-50	3 (6)	6.3	80.7	90.0
51-100	14 (28)	2.9	63.8	89.2
101-150	15 (30)	4.3	95.1	90.7
151-200	9 (18)	4.9	65.4	85.6
> 200	6 (12)	4.7	66.3	83.3

*CD4 decreased from baseline

(II) Clinical response.

The mean weight increased from 54.5 kg to 58.7 kg and this increase was statistically significant, p value: 0.0005. Similarly, the mean (BMI) significantly increased from 20.4 kg/m² to 21.9 kg/m², p-value: 0.001. The mean Karnofsky performance increased from 88.6% to 95.2% and this increase was statistically significant, p-value: 0.0004. Table IV shows treatment outcomes of survivors who had a repeat CD4 at six months.

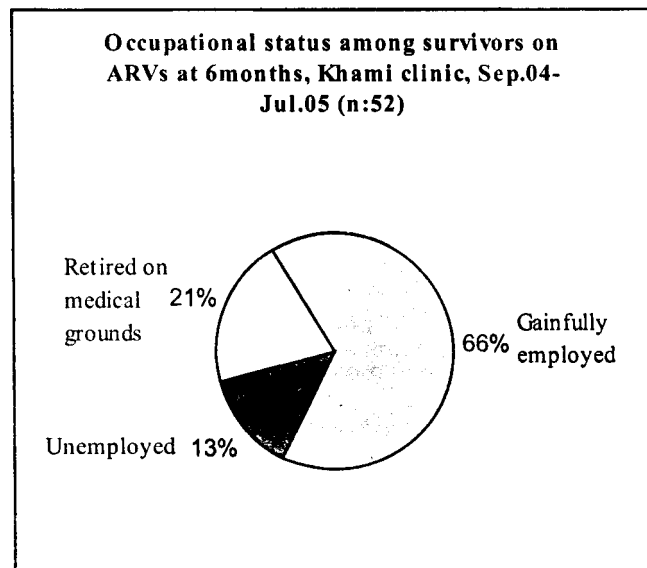
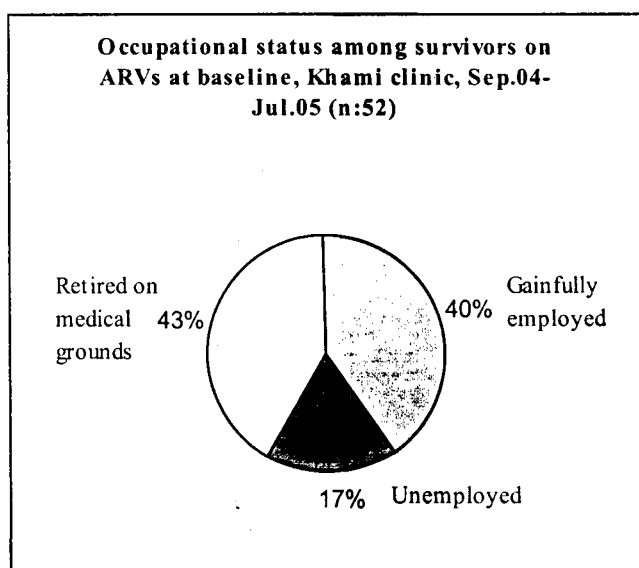
Table IV: Changes in CD4 count from baseline after ARV initiation in relation to other variables among survivors on ARVs at Khami clinic.

Variable	Mean at baseline	Mean at 6 months	*t-statistic	**p value
CD4 count (/mm ³)	79.8	199.9	-10.4	0.0003
Weight (kg)	54.5	58.7	-6.5	0.0005
BMI (kg/m ²)	20.4	21.9	-6.2	0.001
Karnofsky performance (%)	88.6	95.2	-7.9	0.0004

*Paired t-test used **95% level of significance used

The occupational status among survivors improved after 6 months of treatment. At baseline, only 21 (40%) were gainfully employed and as many as 22 (43%) had retired from work on medical grounds. At six months, the proportion of those gainfully employed increased to 34 (66%). Half (11/22) of those who had retired from work on medical grounds had gone back to work at six months. Figure 1 shows changes in occupational status from baseline.

Figure 1: Changes in occupational status among survivors from baseline.



Treatment Adherence and Follow Up.

Among survivors, seven (16%) reported that they missed at least a dose of their medication in the six months. The most frequently mentioned reason was forgetfulness. Overall, each subject took their

medication between 95 % and 100% of the time. Nineteen (37%) reported that at times more than 30 minutes may elapse before taking medication and 23 (44%) reported they had no one reminding them to take their medication. Only two (4%) felt that the quantity of

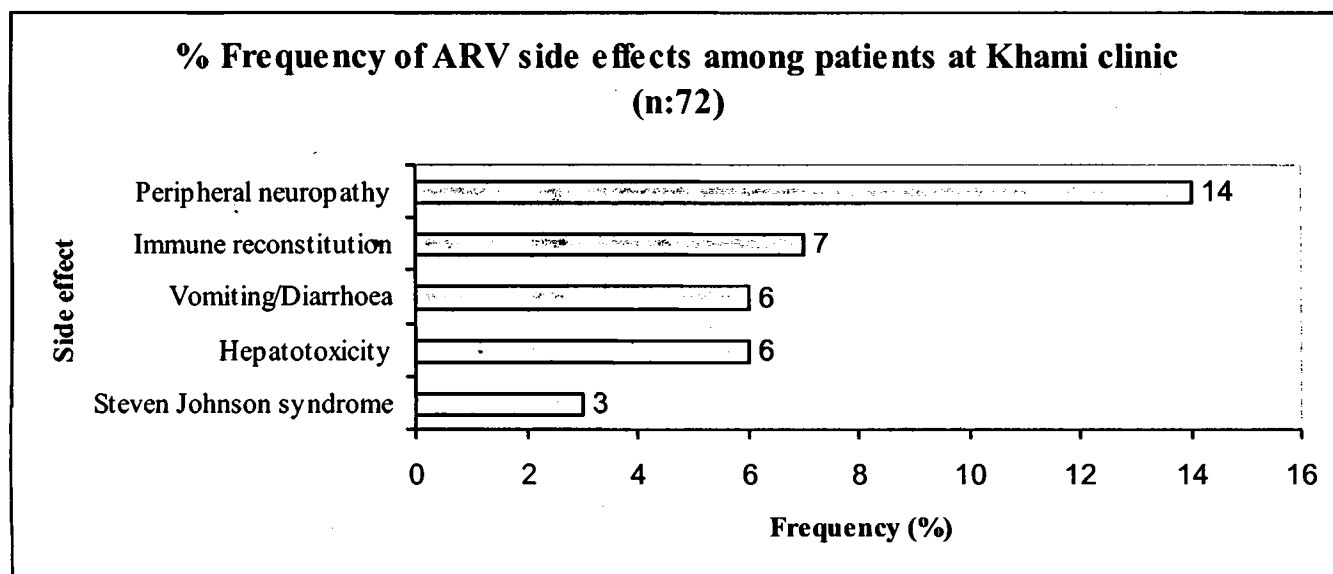
tablets taken per day was too much.

Only four (8%) reported ever missing a review date in the six months, either because they had forgotten the review date or had to attend some social event. Twenty (39%) found coming for review was too expensive, similarly 20 (39%) preferred to be reviewed at their local clinic to minimize transport expenses.

Experienced Side Effects to ARVs.

The frequency of side effects among all 72 subjects was

Figure II: Frequency distribution of side effects.



Household Food Security.

Among the survivors, the median size of household was four; $Q_1=3$; $Q_3=6$. Twelve (23%) reported they had less than three (two or one) as the average number of meals taken per day and 19 (37%) reported that they at times missed meals because they had nothing to cook during the six months of treatment. Fifteen (29%) reported they had no vegetable garden and 45 (87%) no fowl run at home.

Public Health Issues.

The proportion reporting having had sex in the last three months was 35% at baseline. This proportion significantly increased to 40% at six months, p value 0.0001. We, however, did not observe any significant increase in consistent condom use at six months from baseline, p value 0.60.

Among survivors, the proportion that reported having slept with a casual partner in the last three months at base line was five (10%), which was not different from the proportion reporting at six months, five (10%).

Only two out of 24 male respondents interviewed at six months could not correctly describe how to use a male condom and as high as 13 out of 28 female respondents could not correctly describe how to use a female condom. When asked at six months how many times a single male condom can be used, six (12%) of all respondents had no clue and as high as 29 (56%) had no idea how many times a single female condom can be

used. 23 (32%). Peripheral neuropathy was the most frequently documented side effect. Four (6%) had to switch on to a different drug combination because of severity of side effects. Figure II shows the frequency distribution of side effects experienced by the study subjects.

used.

At six months, 20 (38%) had a regular sex partner. Of these three (15%) had not disclosed their status to their partner. Among those who had disclosed status to their regular partner, reasons for disclosure were to protect their partner by engaging in protected sex and to help their partner to enroll into the ARV programme. Among those with a regular partner at six months, 16 (80%) had their partner enrolled into the ARV programme at the time of the exit interview.

Five (10%) reported they at times shared their drugs with someone, usually a spouse also on ARVs and five (10%) reported they at times took alcohol during the six months under review.

Discussion

Bulawayo City introduced an ARV programme at one of its municipal clinics in September 2004. Potential beneficiaries were previously treated TB patients, their spouses and children. The focus of this study was to describe treatment outcomes of these patients after six months of treatment.

Treatment Outcomes.

Among the 52 subjects who were alive at six months, results of this study indicate favorable outcomes for most variables measured at six months compared to measurements at baseline. The mean change in CD4

count was an increase of 120 cells/mm³. This is consistent with expected changes in patients with optimal ARV therapy. The CD4 count is expected to increase by more than 100 cells/mm³ in the first 6 to 12 months on ARVs.¹⁰ Similarly, the mean weight and mean body mass index significantly increased by 4.2 kg and 1.5 kg/m² respectively. Findings, however, fall short of outcomes observed in a similar project in Khayelitsha, South Africa, where outcomes there were more favorable: The mean CD4 cell count change from baseline was observed to be 133 cells/mm³ and the mean weight gain, 6.1 kg at six months. Only 12 % died in the first six months of treatment unlike in our study where mortality was twice as high.¹¹

Treatment Adherence.

Favourable treatment outcomes observed in this study were coupled with very high rates of treatment adherence, of above 95%. These findings are consistent with findings by Orel, *et al.* in Cape Town, who found rates of adherence as high as 93.5%.¹¹ Very high levels of adherence to lifelong Highly Active Anti-retroviral Treatment (HAART) are a pre-requisite for a successful virological and immunological response.¹³ Levels of adherence below 95% have been associated with poor virological and immunological response. For the individual, low levels of adherence are associated with the development of viral resistance, treatment failure and disease progression. From a public health perspective, the emergence of resistant strains of HIV due to poor ARV adherence is likely to result in an increase in the transmission of resistant virus to newly infected individuals.¹³

The concept of a treatment partner who supervises treatment at home was observed as a critical programmatic component of the Khami project. This is consistent with observations in similar projects elsewhere. The Botswana ARV programme is successfully employing a "buddy system" where each patient is encouraged to form a special bond with someone who makes sure they take their medication.¹⁴ In the Khayelitsha project, adherence support involves a treatment assistant, usually someone living in the patient's household, who can assist with adherence issues.¹¹ We, however, observed in our study, that though all patients had brought a treatment partner as a pre requisite for initiation of treatment at baseline, as high as 44% reported they had no one reminding them to take their medication at six months.

Drug side effects.

The incidence of side effects severe enough to require change in treatment was uniformly low. Only 6% had to switch on to a different drug combination because of severity of side effects. This is consistent with observations in the Khayelitsha project, where 8% of patients needed to change an individual drug due to adverse events.¹¹

Tuberculosis is the commonest opportunistic infection encountered among persons with HIV in

Zimbabwe.⁶ Studies have shown that up to 50% of persons with HIV infection develop TB and that up to 85% of persons with TB have HIV infection.¹⁵ The treatment of HIV in those co-infected with HIV and TB has conventionally been deferred because of concerns for drug interactions with rifampicin in particular, which may potentially increase the incidence of drug reactions and toxicity.¹⁵ These fears are reiterated in the Khami clinic project, where those with active TB treatment are deferred until they complete TB treatment. The implications are that, these very ill patients, invariably in WHO stage three and four of AIDS are conveniently delayed in being initiated on these potentially life saving drugs. However, current and recently revised CDC guidelines indicate that rifampicin can be given concurrently with certain non-nucleoside reverse transcriptase inhibitors, like efavirenz, in patients being treated for TB.¹⁵ Guidelines for antiretroviral therapy in Zimbabwe recommend that ARVs be commenced in those patients with extra-pulmonary TB or any TB patient with a CD4 count less than 200 cells/mm³.¹⁶

Household Food Security.

More than a third of respondents reported that they at times missed meals because they had nothing to cook during the six months of treatment. These observations raise pertinent questions on household food security. It is clear, a substantial proportion face food scarcity at household level, which has a negative impact on treatment outcomes. The relationship between HIV and malnutrition presents a classic example of the "vicious cycle" of immune dysfunction, infectious disease and malnutrition. Any immune impairment that results from HIV infection leads to immune impairment, worsens the effect of HIV and contributes to more rapid progression to AIDS.¹⁷ An HIV infected person requires an additional energy intake of 10 to 15%.¹⁷

Public Health Concerns.

Among 20 patients who had a regular sex partner at six months, three (15%) had not disclosed their status to their sexual partner. Among those who had disclosed, some of the reasons for status disclosure were to protect their partner by engaging in protected sex and to help their partner to enroll into the ARV program. This is consistent with observations by Simoni *et al.* who found that ethical responsibility and concern for partner's health was the major reason cited for disclosing to sexual partners.¹⁸

Within HIV testing and counseling programmes, emphasis is placed on the importance of status disclosure among HIV infected clients, particularly to their sexual partners.¹⁹ Disclosure is an important public health goal for a number of different reasons. Disclosure may motivate sexual partners to seek testing, change behavior and ultimately decrease transmission of HIV.¹⁹

Exposure to the Khami project did not change the proportion who reported having slept with a casual

partner in the last three months at six months, compared to observations at baseline. Neither was there any significant increase in consistent condom use from baseline, *p* value 0.60. These findings are a sharp contrast to observations in Khayelitsha, where the ARV project resulted in a significant increase in uptake of HIV prevention interventions such as HIV testing and counseling, and condom use.¹¹ As many as 13 (46%) of 28 female respondents could not correctly describe how to use a female condom and more than 50% of all respondents had no idea how many times a single female condom can be used. This knowledge gap represents the magnitude of neglect in empowering the female gender in having some degree of control over the sexual act and promoting use of a female condom.

Among those interviewed at six months, 10% reported they at times shared their drugs with someone, usually a spouse also on ARVs. This disturbing phenomenon, if left unchecked, has the potential to compromise optimal treatment adherence. Muula *et al.* in Malawi also observed pill sharing with a spouse prevalent among patients on ARVs.²⁰

Conclusion.

The Khami ARV project in Bulawayo bears testimony that even in a resource poor Primary Health care setting, treatment of HIV/AIDS with ARV drugs is feasible. This has been evidenced by favorable clinical outcomes among survivors despite challenges in household food security.

Of public health concern is that there were no significant changes in casual sex partnering and consistent condom use after six months of exposure to the programme.

It is regrettable that the programme offers only a first line treatment regimen with no salvage regimen in case of treatment failure and there is no laboratory capacity to detect drug resistance. However, it should be noted that there are only a few public health facilities in the country that offer second line salvage regimens.

Recommendations.

There is need to initiate ART to eligible TB patients according to national guidelines so as to improve prognosis. The authors recommend that the city health directorate engage social welfare and donor partners to economically empower patients on ARVs through income generating projects so as to ensure household food security, to maximize treatment outcomes.

Khami Clinic staff need to reinforce counseling on reduction of risky behavior, with emphasis on casual sex partnering and consistent condom use. Equipping female patients on how to use a female condom could go a long way in empowering them to have some measure of control over their sex life. There is urgent need to decentralize patient reviews to alleviate transport costs on patients.

The authors also recommend a study to assess to

what extent quality of care relates to treatment outcomes and mortality at the Khami Clinic setting.

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